

REMARKS

Applicants amend claims 1, 19, 33, 50, 52-54, and cancel claims 49 and 51 without prejudice. As discussed in more detail below, support for the amendments can be found in the specification. Application is believed to be in condition for allowance. Reconsideration and allowance are respectfully requested.

Rejections Under 35 U.S.C. 112

In response to the rejection of claim 19 for lack of sufficient antecedent basis for the phrase “said tubing,” this phrase is amended to recite “said tubular article.” This amendment is believed to overcome the rejection.

Rejections Under 35 U.S.C. 102(b)

The Office Action rejects claim 49 as being anticipated by U.S. Patent No. 5,601,883 of Yamazaki.

Claim 49 is canceled without prejudice, as indicated above. Accordingly, its rejection is not discussed any further. Applicants reserve the right to pursue this claim in future continuing applications.

Rejections Under 35 U.S.C. 103

The Office Action rejects claims 1, 4-8, 10-19, 21-28, 31, 33-39 and 49-52 as being obvious over U.S. Patent No. 5,601,883 of Yamazaki in view of U.S. Patent No. 5,914,115 of Subramanian, and optionally considering U.S. Patent No. 5,053,244 of Kieser and/or U.S. Patent No. 4,897,285 of Wilhelm.

Claim 1, as amended, recites a method of treating an inner surface of a tubular article having a lumen that comprises the steps of: generating a gaseous plasma within a spatially-localized region of space by electron cyclotron resonance, exposing *an inner surface* of the lumen of the tubular article to the plasma for a selected time period to treat the surface, and *subsequently*, coating the treated surface with a selected material. Support for the amendments to claim 1 can be found, e.g., on page 7, and throughout the remainder of the specification.

Yamazaki discloses a chemical vapor deposition method for coating *external* surfaces of articles, which includes a step of cleaning such a surface via exposure to a plasma generated in a gas by microwave energy and a magnetic field and depositing carbon on the surface. Yamazaki does not teach or suggest applying its method to internal surfaces of the articles. Nonetheless, the Examiner states that it would not be unreasonable to suppose that application of Yamazaki's method to tubular articles could result in plasma treatment and coating at the ends or edges of their lumens "since gas would inherently be present in their interiors..."

In other words, the Examiner appears to suggest that Yamazaki's method inherently provides plasma treatment and coating of at least a portion of an inner surface of a tubular article. A two-prong rule established by the Court of Appeals for the Federal Circuit (CAFC) for anticipation by inherency requires the following: (i) the "missing descriptive matter is necessarily present in the thing described in the reference," and (ii) "it would be so recognized by persons of ordinary skill." *Continental Can Co. USA, Inc. v. Monsanto Co.* 948 F.2d 1269 (Fed. Cir. 1991).

Yamazaki's teachings do not comply with any of these requirements. As an initial matter, there is no guarantee that the plasma parameters utilized in Yamazaki would result in generation of a plasma at ends or edges of lumens, if any, of the articles. Moreover, Yamazaki is only concerned with treating external surfaces of articles, and not their internal surfaces. As such, one of ordinary skill in the art would not find any teaching in Yamazaki directed to plasma treatment of internal surfaces of articles.

Furthermore, claim 1 is amended to recite that an inner surface of the lumen of the tubular article, rather than at least a portion thereof, is exposed to the plasma. Even if one assumes *arguendo* that the Examiner's supposition regarding generation of plasma at edges or ends of luminal surfaces of the articles in Yamazaki is correct, such edge or end plasmas would not extend to the entire inner surfaces of the lumens of these articles.

Moreover, Subramanian does not bridge the gap in the teachings of Yamazaki. Subramanian utilizes an RF glow discharge for functionalizing a surface of a medical device, which can then be contacted with a bioactive agent. In contrast, the claimed method recites

employing an ECR plasma to treat an inner surface of the lumen of a tubular article. An RF glow discharge is, however, difficult to maintain within the lumen of a tubular article, especially one having a small diameter, and hence does not provide the advantages of an ECR plasma for such applications.

In addition, there is no motivation to replace the RF glow discharge of Subramanian with an ECR plasma. The Examiner points to certain passages of Yamazaki, which indicate that RF glow discharges or arc discharges can be also be utilized in its cleaing step, to conclude that Yamazaki teaches equivalence of these discharges with an ECR plasma. These passages, and in fact the entire disclosure of Yamazakis, relate to cleaning and coating *external* surfaces of articles, and *not* their internal surfaces. Yamazaki simply does not contemplate utilizing a plasma for treating inner surfaces of articles. As such, it does not teach equivalence of one plasma method with another in the context of treating inner surfaces of the lumens of tubular articles.

Kieser and Wilhelm do not cure the shortcomings of Yamazaki and Subramanian. In particular, both kieser and Wilhelm describe methods for direct deposition of a coating material from a plasma onto a surface, and not the two-step process of claim 1 that includes initially treating an inner surface of a lumen with an ECR plasma and *subsequently* coating the treated surface.

Accordingly, claim 1, and claims 4-8, 10-19, 21-28, and 31 that depend either directly or indirectly on claim 1 are patentable.

Independent claim 33 recites a method of treating an inner wall of an electrically non-conducting lumen, comprising the steps of: placing a selected portion of said lumen in a treatment zone, applying a magnetic field having a selected strength to the treatment zone, introducing a gas into said lumen within said selected portion, said gas being in contact with the inner wall of said selected portion, irradiating said gas with electromagnetic radiation having a frequency selected to be substantially equal to electron cyclotron frequency at said selected magnetic field strength so as to ionize said gas and create a plasma zone within said selected portion, said plasma treating said inner wall of the lumen *so as to cause a physical and/or*

chemical modification of the inner wall, and subsequently, coating said treated inner wall with a selected material.

Support for the amendments to claim 33 can be found, e.g., on page 8, and throughout the remainder of the specification.

As discussed in detail above, Yamazaki does not teach treating inner surfaces of tubular articles with an ECR plasma. Further, even if one assumes that the application of Yamazaki's plasma cleaning step results in generation of plasmas at the ends or edges of lumens of tubular articles, there is no indication that these plasmas would be sufficiently strong to cause a physical and/or chemical modification of such luminal surfaces. In other words, Yamazaki neither expressly or inherently teaches modifying physical and/or chemical characteristics of at least a portion of an inner surface of the lumen of a tubular article by exposing the surface to an *ECR* plasma. Further, none of the other cited references (Subramanian, Kieser or Wilhelm) does bridge this gap in the teachings of Yamazaki. In particular, as noted above, Subramanian does not disclose utilizing an ECR plasma for treating the surfaces of its medical devices. Further, Kieser and Wilhelm do not disclose the two-step process recited in claim 33.

Hence, claim 33 and claims 34-39 and 51 and 52, which depend either directly or indirectly on claim 33, distinguish patentably over the cited references.

As noted above, claim 49 is canceled without prejudice, and hence its rejection will not be discussed any further.

Independent claim 50, as amended, recites a method of treating an inner surface of a lumen of each of a plurality of tubular articles, comprising: generating a gaseous plasma within a spatially-localized region of space by electron cyclotron resonance, simultaneously exposing a portion of an inner surface of each of the articles to said plasma for a selected time period to treat the surfaces *so as to physically and/or chemically modify them, and subsequently, coating said treated surfaces with a selected material.*

The arguments presented above with respect to claim 33 apply with equal force to establish that claim 50 is also patentable.

In Paragraph 7 of the Office Action, claims 21-24 and 26-28 are rejected as being obvious over Yamazaki in view of Subramanian, optionally considering Kieser or Wilhelm, and further in view of U.S. Patent No. 4,927,676 of Williams, U.S. Patent No. 5,942,277 of Makker and U.S. Patent No. 5,486,357 of Narayanan.

These claims depend either directly or indirectly on claim 1, and hence incorporate its patentable features. As discussed in detail above, claim 1 (and hence its associated dependent claims) distinguish over the combined teachings of Yamazaki and Subramanian. Williams, Makker and Narayanan do not cure the shortcomings of Yamazaki and Subramanian. Williams, which is generally directed to forming a confluent layer of endothelial cells over a polymeric substrate functionalized by exposure to a nitrogen-containing plasma, does not teach utilizing an ECR plasma for functionalizing the surface. Likewise, Narayanan fails to teach utilizing an ECR plasma for treating a surface, but rather discloses treating polymeric surfaces with a radiofrequency generated plasma. Similarly, Makker employs a radiofrequency generated plasma, rather than an ECR plasma, to treat a polymeric surface.

In Paragraph 8, the Office Action rejects claims 1, 4, 8, 10, 16-17, 19, 21-22, 24-25, 27-28, 31, 33, 36 and 49-52 as being anticipated by U.S. Patent No. 6,136,389 of Conover.

Conover discloses a method for preparing thin films of noble metals on porous substrate surfaces in which metal containing monomer or comonomer precursors are dissociated by a glow discharge and deposited as a platinized coating over the surface.

Conover does not teach initially treating the surface with a plasma and subsequently, in a separate step, depositing the metal over the surface. Rather, the plasma is utilized to cause the deposition of the metal. In contrast, amended claim 1 recites that the coating step is performed *subsequently* to treating the inner surface of the lumen with a plasma. Such a two-step process of treating a surface followed by coating can advantageously provide enhanced flexibility.

Hence, claim 1 and claims 4, 8, 10, 16, 17, 19, 21-22, 24-25, 27-28, and 31, which depend either directly or indirectly on claim 1, are patentable over Conover. Further, similar arguments apply to establish that independent claim 33, which also recites a two-step process of treating an inner wall of a lumen with a plasma and subsequently coating the treated surface, is also patentable over Concover. Likewise, claims 36, and 52 (claim 51 is canceled as indicated above) are patentable as they depend on claim 33 and hence incorporate its patentable features.

Similar arguments also apply to establish that independent claim 50, as amended, also distinguishes patentably over Conover. In particular, similar to claim 33, claim 50 recites that plasma treatment of the inner surfaces and coating of the treated surfaces are performed in two separate steps – a feature not taught by Conover.

In Paragraph 9, the Office Action rejects claims 5-7, 11-15, 22, 25-26, 34-35 and 37 as being obvious over Conover.

Claims 5-7, 11-15, 22, 25-26 depend either directly or indirectly on independent claim 1, and claims 34-35 and 37 depend on independent claim 33. As discussed above, claims 1 and 33 distinguish patentably over Concover, and hence so do their associated dependent claims, which incorporate their patentable features.

In paragraph 12 of the Office Action, claims 53-58 as being unpatentable over Conover in view of Wilhelm and U.S. Patent No. 5,967,257 of Kanai.

Independent claim 53 recites a method of selectively treating an internal surface of a tubular article having a lumen, comprising: placing at least a portion of the tubular article in a treatment zone to which a magnetic field having a selected strength is applied, introducing a gas into the article's lumen so as to generate an internal pressure different than an external pressure to which an outer surface of said portion is exposed, irradiating the tubular portion with electromagnetic radiation having a frequency selected to be substantially equal to electron cyclotron frequency at said magnetic field strength so as to generate a plasma within said lumen portion for treating a surface thereof, wherein said external pressure inhibits formation of a

plasma in proximity of the outer surface, and subsequently, coating said treated lumen surface with a selected material.

Conover does not teach or suggest generating a differential pressure between the inner and outer portions of a tubular article so as to selectively expose the article's outer surface to an ECR plasma while inhibiting plasma generation within the article's lumen. The passage of Conover to which the Examiner refers describes different chemical deposition techniques, and not utilizing a pressure differential between inner and outer portions of a tubular article to control generation of plasma in those portions. Moreover, as noted above, Conover does not teach treating a surface by a plasma, and in a separate step coating the treated surface.

Further, Wilhelm is not concerned with differential coating of an inner and an outer surface of a tubular article. Rather, it is directed to direct plasma coating of an inner surface of a microwave waveguide. As such, it does not provide any teaching pertinent to the subject matter of claim 53. Further, Kanai does not cure the shortcomings of Conover and Wilhelm in this regard. In particular, the passage in Kanai to which the Examiner refers simply describes utilizing a mesh member to prohibit microwave leakage through an exhaust port of a CVD apparatus while permitting gas exhaust through the port.

Hence, claim 53 distinguishes patentably over the cited art.

Similar argument apply to establish that independent claim 54 and claims 55-58 dependent thereon are also patentable over the cited art.

CONCLUSION

In view of the above amendment, Applicants request reconsideration and allowance of the application.

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